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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,949	08/12/2003	Rajat Sethi	12695.6USD5	6992

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EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/639,949		SETHI ET AL.	
	Examiner		Art Unit	
	Dwayne C. Jones		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19SEP2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-6 are pending.
2. Claims 1-6 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claim 1-6 have been considered and found persuasive to include additional support for the combination of a well known thrombolytic agents, such as aspirin and heparin, along with a multivitamin that happens to contain vitamin B₆. Accordingly the arguments of September 19, 2005 have been considered and a subsequent Office Action has been made to address the issues it raised.
4. In particular, applicants argue that there is no motivation to combine these references of record, namely Hardman, J.G. in view of Pollack et al. also in view of Dakashinamurti et al. The prior art reference of Hardman, J.G. specifically discloses to the skilled artisan that it is well known in the art to administer anticoagulants and antiplatelet drugs for the treatment of a variety of ailments, such as thrombolytic disease, myocardial infarction, stroke. Hardman, J. G. disclose of the using heparin and aspirin to reduce the development a blockage due to an embolism or clot due to their anticoagulant and/or antiplatelet properties, (see page 1354-1357). Next, the prior art references of Pollack et al. and of Dakashinamurti et al. are provided to show to the skilled artisan that vitamin B₆ and its structurally related compounds like are known.

Art Unit: 1614

Dakashinamurti et al. teach that it is known in the art that vitamin B₆ derivatives are pyridoxal-5-phosphate, pyridoxal, pyridoxamine, 4-pyridoxic acid, (see column 3, lines 18-23). The skilled artisan knows that vitamins, namely and including vitamin B₆, are needed and required for many metabolic steps and biochemical processes in higher animals, which includes humans. For these reasons, one having ordinary skill in the art would have found it obvious to include a multivitamin or a vitamin supplement of B₆ to maintain basic metabolism of a healthy individual, especially when vitamins, including B₆, are not synthesized by a human and need to be taken as a supplement to a one's diet, even when a person is being treated with ailment such as reducing blood clots to obviate blockages thus causing infarcts. In fact, the prior art reference of Stryer specifically teaches to the skilled artisan to supplement the diet of a human with vitamins that includes pyridoxine, which is a form of vitamin B₆, because vitamins are essential to basic human metabolism and need to be supplemented into a person's diet. Clearly, one having ordinary skill in the art would have been motivated and found it obvious to reduce blood clots with an antithrombolytic agent, such as heparin or aspirin, along with a multivitamin or even a vitamin supplement of B₆ in order to maintain the overall health of an individual by allowing metabolic processes to function while in the presence of a vitamin, such as vitamin B₆ along with obvious derivatives of vitamin B₆, such as pyridoxal-5-phosphate, pyridoxal, pyridoxamine, 4-pyridoxic acid, as taught by Stryer and Dakashinamurti et al. Consequently, the instant claims are rendered obvious over Hardman, J.G., Editor-in-Chief of Goodman & Gilman's THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 9TH EDITION in view of Pollack et

Art Unit: 1614

al. of U.S. Patent No. 2,904,551 and also in view of Dakashinamurti et al. of U.S. Patent No. 6,051,587 in further view of Stryer.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1614

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman, J.G., Editor-in-Chief of Goodman & Gilman's THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 9TH EDITION in view of Pollack et al. of U.S. Patent No. 2,904,551 and also in view of Dakashinamurti et al. of U.S. Patent No. 6,051,587 still in further view of Stryer.

9. Hardman, J.G., Editor-in-Chief of Goodman & Gilman's THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 9TH EDITION disclose to the skilled artisan that it is well known in the art to administer anticoagulants and antiplatelet drugs for the treatment of a variety of ailments, such as thrombolytic disease, myocardial infarction, stroke. Hardman, J. G. disclose of the using heparin and aspirin to reduce the development a blockage due to an embolism or clot due to their anticoagulant and/or antiplatelet properties, (see page 1354-1357).

10. The prior art reference of Pollak et al. is provided to show that vitamin B₆ is pyridoxine, (see column 1, lines 21). Next, Dakashinamurti et al. teach that it is known in the art that vitamin B₆ derivatives are known. Dakashinamurti et al. teach that it is known in the art that vitamin B₆ derivatives are pyridoxal-5-phosphate, pyridoxal, pyridoxamine, 4-pyridoxic acid, (see column 3, lines 18-23). The prior art teaches of the administration of anticoagulants and antiplatelet drugs as well as vitamin B₆ and its derivatives, namely pyridoxal-5-phosphate, pyridoxal, pyridoxamine, 4-pyridoxic acid. Although the prior art of record does not specifically teach of using vitamin B₆ to reduce blood clots, it would have been obvious to the skilled artisan to arrive at the instantly claimed subject matter by simply combining known anticoagulants and antiplatelet drugs

Art Unit: 1614

(namely heparin and aspirin) for the treatment of a variety of ailments, such as thrombolytic disease, myocardial infarction, stroke (as evidenced by Hardman, J. G.) along with a vitamin supplement of the well known and needed vitamin of vitamin B₆. The instantly claimed subject matter is rendered obvious to one of ordinary skill in the art especially when known compounds, such as heparin and aspirin, are combined with the administration of a vitamin B₆ supplement as well as its chemical variants, namely vitamin B₆ derivatives are pyridoxal-5-phosphate, pyridoxal, pyridoxamine, 4-pyridoxic acid.

11. The skilled artisan knows that vitamins, namely and including vitamin B₆, are needed and required for many metabolic steps and biochemical processes in higher animals, which includes humans. For these reasons, one having ordinary skill in the art would have found it obvious to include a multivitamin or a vitamin supplement of B₆ to maintain basic metabolism of a healthy individual, especially when vitamins, including B₆, are not synthesized by a human and need to be taken as a supplement to a one's diet, even when a person is being treated with ailment such as reducing blood clots to obviate blockages thus causing infarcts. In fact, the prior art reference of Stryer specifically teaches to the skilled artisan to supplement the diet of a human with vitamins that includes pyridoxine, which is a form of vitamin B₆, because vitamins are essential to basic human metabolism and need to be supplemented into a person's diet. Clearly, one having ordinary skill in the art would have been motivated and found it obvious to reduce blood clots with an antithrombolytic agent, such as heparin or aspirin, along with a multivitamin or even a vitamin supplement of B₆ in order to maintain the

Art Unit: 1614

overall health of an individual by allowing metabolic processes to function while in the presence of a vitamin, such as vitamin B₆ along with obvious derivatives of vitamin B₆, such as pyridoxal-5-phosphate, pyridoxal, pyridoxamine, 4-pyridoxic acid, as taught by Stryer and Dakashinamurti et al.

12. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Clearly, one having ordinary skill in the art would have been motivated from the prior art teachings to simply combine already known pharmaceutical known anticoagulants and antiplatelet drugs (namely heparin and aspirin) along with vitamin B₆, and its structurally-related compounds vitamin B₆ derivatives are pyridoxal-5-phosphate, pyridoxal, pyridoxamine to reduce blood clot formation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

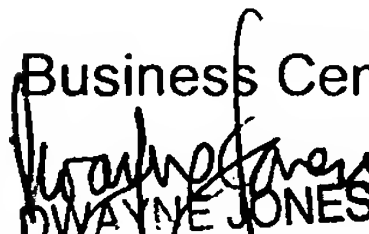
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Art Unit: 1614

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

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Business Center (EBC) at 1-866-217-9197 (toll free).


DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
December 16, 2005